JUL 2 5 2002

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K 022085.

1) Submitter Information

Submitter's Name:	J&S Medical Associates
Address:	35 Tripp Street, Bldg.1 Framingham, MA 01702
Contact Person:	Dr. Paul MacDonnell
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Fax:	(508) 370-4554
Establishment Registration Number:	1218982
Date Prepared:	06/24/2002

2) Identification of Device

Device Name:	Urine Dipstick Control
Proprietary/ Trade Name:	J&S Medical Sentry Urine Dipstick Control
Common Name:	Urinalysis Controls
Classification Name:	Urinalysis Controls (Assayed and Unassayed)
Device Classification:	1
Regulation Number:	21 CFR 862.1660
Panel:	Clinical Chemistry
Product Code:	JJW

3) Identification of the Predicate Device:

Predicate Device Name:	The Dropper urine dipstick control
Manufacturer:	Quantimetrix Corporation
510(k) #:	Unknown

4.0 Description of the Device

The three Sentry controls are prepared with human and animal proteins and with various chemical additives. These chemicals interact with the dipstick reactant pads to produce specific color changes that mimic actual normal and/or abnormal urine samples.

4.1 Sentry Level 1 Control is designed to test positive for leukocytes, nitrite, urobilinogen, protein, blood, ketone, bilirubin, and glucose with dipsticks. In addition, this control will have a pH of about 7 with an elevated specific gravity and will test positive for hCG.

4.2 Sentry Level 2 Control is designed to test positive for ascorbic acid, have a pH of about 5, and a moderately elevated specific gravity.

4.3 Sentry Level 3 Control is designed to have a pH of about 7 with a low specific gravity.

5.0 Intended Use

The controls are intended to be used by laboratory technicians in order to verify the performance of urine dipsticks made by various companies.

6.0 Substantial Equivalence

6.1 The Sentry Urine Dipstick Controls (Levels 1, 2, and 3) and the Quantimetrix Controls (Level 1 and 2) are supplied as liquids and do not require further treatment before use.

6.2 The Sentry and Quantimetrix controls are used to verify the performance of various urine dipsticks.

6.3 The Sentry and the Quantimetrix Controls will have value assignments to account for variations in manufacturers' dipstick formulations.

7.0 Assignment of Expiration date

7.1 Samples of the three controls were incubated at 4° C, ambient (for open vial room temperature stability), 25° C, and 37° C for 65 days.

7.2 The stability of the three controls were assessed as follows:

7.2.1 Solutions were tested at frequent intervals using Quidel dipsticks. The results were recorded visually by comparing reactant pad color intensity to the color chart supplied by Quidel; the results also were measured with the Behring Rapimat II instrument. After 65 days incubation of the controls at 37°, all of the controls performed within specifications, indicating a shelf life of two years for the three controls (Table I).

7.2.2 The stability of the controls also was assessed by testing with Bayer dipsticks visually and with the Bayer Clinitek 100 instrument. The stability data with the Bayer strips are similar to that with the Quidel strips indicating an expiration date of two years for the three controls (Table II).

7.2.3 The stability of hCG in Sentry Level 1 was assessed by testing the solution at periodic intervals up to 120 at days 4°, 25°, and 37° C. When tested with Quidel QuickVue One-Step hCG Combo lateral flow device a positive response was detected after 120 days. An expiration date of two years can be assigned (Table III).

8.0 Open vial stability of Sentry Controls 1, 2, and 3

Samples of the Sentry Urine Dipstick Control Levels 1, 2, and 3 were stored at ambient temperature (19° C to 22° C). Quidel dipsticks and Bayer dipsticks were used to test the controls at periodic intervals for 65 days. At day 65, the controls reacted within specifications, indicating open vial shelf life of at least two months for the three controls (Tables IV, V)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Joslyn S. Murphy
Quality Assurance Manager
J&S Medical Associates
35 Tripp Street, Bldg. 1
Framingham. MA 01702

Re: k022085
Trade/Device Name: Sentry urine dipstick control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJW
Dated: June 24, 2002
Received: June 27, 2002

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K022085

Device Name: Sentry urine dipstick control

Indications for Use:

J&S Medical Associates Sentry dipstick urine controls are intended to be used by laboratory technicians in order to verify the performance of various urine dipsticks as a part of the laboratory's quality control practices.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022085

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Description Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)